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10/697,655	10/31/2003	Michael Weller	NGIO-001	1173

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EXAMINER	
KLINKEL, KORTNEY L	
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1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,655	WELLER ET AL.	
	Examiner	Art Unit	
	Kortney Klinkel	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 26-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 26-35* is/are rejected.

7)☒ Claim(s) *11-14,26,30 and 32-34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims

Acknowledgement is made of Applicant's cancellation of claims 16-25 and 36-42 in an amendment dated June 16, 2008.

Claims 1-15 and 26-35 are pending in the instant Office action.

Election/Restriction

Applicant's election with traverse of Group I, claims 1-15 and 26-35 in the reply filed on June 16, 2008 is acknowledged. The traversal is on the ground(s) that the Examiner failed to show sufficient burden. This is not found persuasive because the invention of group I, II and III have acquired separate status in the art in view of their different classifications. Additionally, the inventions of groups I, II and III are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph.

Acknowledgement is also made of Applicant's election of the compound 2-[[3-(3,4-dimethoxyphenyl)-1-oxo-2-propenyl]amino]benzoic acid, hereafter referred to as tranilast.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states,

"the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Applicants are respectfully reminded of their duty to disclose, please reference MPEP 2000 including 37 CFR 1.56.

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/422504, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The provisional application filed October 21, 2002 does not provide adequate support or enablement for lipopolysaccharide-induced nitric oxide synthesis. Accordingly, claims 5 and 10 as well as claims dependent on claim 10, namely 11-15 are not entitled to the benefit of the prior application.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because Figure 1 is illegible. The copy of Figure 1 that was submitted is nearly blank and fails to show any data. Figure 2, which contains images of Northern blots, is so dark that the bands are illegible. Figure 3 is also so dark that the bands cannot be discerned. Additionally the labels on the graphs is also darkened and blurred so that they are difficult to impossible to read. The bands depicted in Figures 4-7 are also so dark that they are unintelligible. The graphical portions of Figures 4-7 are up to standard. The images in Figure 8 are also so dark that the bands cannot be discerned. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the

replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 11-14, 26, 30 and 32-34 are objected to because of the following informalities:

Claim 11, C1-C4 alkyl or C1- C4 alkoxy should read C_1-C_4 alkyl or C_1-C_4 alkoxy.

Claim 12, R1and R2 are hydrogen should read R^1 and R^2 are hydrogen, also selected from C_1 –C4 alkoxy should read C_1-C_4 alkoxy.

Claim 13 and 33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 or 33, upon which 13 and 33 depend respectively, states that the carboxyl group is in the 2-position. The figure in claim 13 and 33 shows that the carboxyl group can be variably attached to the ring.

Claims 14 and 34 recite "…-2-propeny1]amino]…", multiple times. This appears to be a simple typo and should recite "…-2-propenyl]amino]…"

Claim 26 is missing a space between C_1-C_4 alkyl and C_1-C_4 alkoxy.

Claim 30 recites "…AIDS dementia. Alzheimer's disease…" There is a period after dementia rather than the necessary comma.

Claim 32 recites C_1-C4alkoxy and should read C_1-C_4 alkoxy.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6, 11-15, 26 and 30-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, independent claims 1, 6, and 26 and thereby dependent claims 11-15 and 31-35 recite the broad recitation microglial cell functional activity, and the claim also recites iNOS expression which is the narrower statement of the range/limitation. iNOS expression is a specific form of microglial cell functional activity.

Claim 30 and thereby dependent claims 31-35 recite the limitation "said neuronal damage". There is insufficient antecedent basis for this limitation in the claim. Claim 30 is dependent upon claim 28 which does not recite any neuronal damage. It is possible that claim 30 should depend on claim 29 rather than 28 because claim 29 does recite neuronal damage.

Claim 26, and thereby dependent claims 31-35 recite the phrase "aberrant, unwanted or otherwise inappropriate microglial cell functional activity". The claim fails to particularly point out and distinctly define the metes and bounds of the subject matter the Applicant's seek to be patented. It is unclear as to how a person possessing ordinary skill in the art could determine when or what of aberrant, unwanted or otherwise inappropriate microglial cell functional activity consists.

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants claim a method for the treatment and/or prophylaxis of a condition characterized by aberrant, unwanted or otherwise inappropriate microglial cell functional activity in a mammal by administering to said mammal an effective amount of a compound of formula (I), specifically tranilast. Subsequent dependent claims state that the microglial cell functional activity is nitric oxide synthesis and that the said condition is nitric oxide induced neuronal damage, specifically brain ischaemia, Parkinson's disease, AIDS dementia, Alzheimer's disease, oligodendrocyte cytotoxicity, demyelination in multiple sclerosis or amyotrophic lateral sclerosis.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

All of these factors have been considered with the most relevant ones discusses below.

The nature of the invention and the breadth of the claims. The nature of the invention is complex in that it is for the treatment or prevention of a condition characterized by aberrant, unwanted or otherwise inappropriate microglial cell functional activity by administering tranilast. The breadth of the claims is extensive and exacerbates the complexity of the invention. With the exception of Claim 35, the claims encompass multiple different compounds of general formula (I), which have different structural and functional characteristics. Claim 26 states aberrant, unwanted or otherwise inappropriate microglial cell functional activity. There are several different microglial cell functional activities. Even the more specific claims 29 and 30 state that the condition is nitric oxide induced neuronal damage, specifically brain ischaemia, Parkinson's disease, AIDS dementia, Alzheimer's disease, oligodendrocyte cytotoxicity, demyelination in multiple sclerosis or amyotrophic lateral sclerosis. The great breadth of the claims means that the invention encompasses very dissimilar embodiments and elements that are structurally and functionally distinct. The above stated conditions encompass several different embodiments and many different etiologies, several of which are unknown even to this day. Many, if not all of these disorders are difficult, and often impossible to predict, prevent and treat.

The state of the prior art and the predictability or lack thereof in the art. The state of the prior art is such that it involves screening both *in vitro* and *in vivo* to determine

which compounds exhibit the desired pharmacological activities (i.e. which compounds treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. Drugs that are used to treat the central nervous system (CNS) face several hurdles. First of all, the drug needs to be able to reach the site of action. There are several natural barriers to drug penetration into the CNS including physical impediments, such as the blood-brain barrier and blood-cerebral spinal fluid barrier, in addition to the presence of drug specific transporters in the cells comprising these barriers. A drug intended for the CNS must cross the blood-brain barrier either via passive diffusion or receptor-mediated transport. Typically the more lipid-soluble a drug, the easier it is for it to successfully penetrate the physical barriers present in the CNS. However, many drug efflux transporters can effectively prevent the accumulation of the substance within the CNS (Löscher and Potschka, Drug Resistance in Brain Diseases and the Role of Drug Efflux Transporters, *Nature Reviews. Neuroscience*, vol. 6, Aug. 2005, 591-602, see specifically the section on Drug efflux transporters in the brain on pages 592 and 593). Nature has put in place a formidable set of barriers to prevent drug penetration into the CNS. Agents targeting conditions characterized by aberrant, unwanted or otherwise inappropriate

microglial cell functional activity, such as neurodegenerative diseases (NDDs), like those enumerated in claim 30 must overcome these barriers in order to be effective. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic and preventive effects of the above listed diseases, whether or not the disease is effected by tranilast and more importantly, if tranilast can even penetrate the blood-brain barrier, would make a difference. In addition, the remainder of the compounds of formula (I) which encompass different structures and the inability in the art to reliably predict the structural/functional characteristics of such molecules makes it difficult to assert any functionality *in vitro*, and certainly not *in vivo*, of these molecules absent evidence.

There is no common mechanism by which all, or even most, NDDs arise. Accordingly, treatments for NDDs are normally tailored to the particular type of NDD, as there is no, and there can be no "magic bullet" against NDDs in general. The pathogenesis of all NDDs is complex. The varied anatomic specificities of each of the NDDs need to be considered.

Take for instance the NDD Alzheimer's disease which is associated with aging, as just one example. It is the state of the art that there is no known cure or prevention for Alzheimer's disease. In fact, the cause of the disease is still not clear. It is well known that the major pathological observations in Alzheimer's disease are β-amyloid deposits and neurofibrillary tangles in the patient's brain. However, it has not been well

established what the molecular mechanisms of the etiology of Alzheimer's disease. Since the prior art has not well deciphered the cause of Alzheimer's disease, it is very difficult to treat the disease without knowing its full scope of etiology and molecular mechanisms.

Microglia, however, are postulated to play a neuropathological role in most neuroinflammatory and NDD. However, little is known about the specific role of microglia in NDDs, and what is known is intricate and complex. Neurotoxic mediators such as free radicals, nitric oxide, cytokines etc. that are released by activated microglia are thought to be the link between neuroinflammatory and neurodegenerative processes in multiple sclerosis, Alzheimer's disease, Parkinson's disease and amyotrophic lateral sclerosis (Rock et al. J. Neuroimmune Pharmacol. vol. 1, 2006, 117-126, Microglia as a Pharmacological Target in Infectious and Inflammatory Diseases of the Brain, pages 121-122 and Table 2 on page 119). The role of microglia are different for various NDD. For instance, Rock et al. teach that in the case of multiple sclerosis, it is postulated that inflammatory mediators (cytokines, chemokines, and free radicals) released from activated microglia contribute to damage of oligodendrocytes (page 112). Activated microglia play a different role in the pathogenesis of Parkinson's disease. It is thought that the generation of reactive oxygen and nitrogen intermediates by activated microglia plays a role in neurodegneration of dopaminergic neurons (the critical site of brain damage in Parkinson's disease), (page 123).

The activation trigger for microglia, however, still remains a mystery. Rock et al. on this topic state, "In most cases, the activating triggers are unknown but may be either

exogenous factors, e.g., microbial products, environmental toxins or neurotoxic drugs, or endogenous proteins that have taken on pathological properties, e.g., amyloid β peptide (Aβ) in AD [Alzheimer's Disease] and α-synuclein in PD [Parkinson's Disease]" (page 122). There is no common mechanism by which microglia activation and subsequent secretion of neurotoxins arise. Accordingly, treatments, when possible, are directed towards the specific NDD.

Microglia play a very complex role in the CNS. Microglia do not simply play a complicated neurotoxic role (as highlighted above) they also exhibit neuroprotective properties. As a result it is clear that not everything is understood about these intricate cells.

The amount of direction or guidance present and the presence or absence of working examples. The specification in Examples 1-2, including Figures 1-8 shows only *in vitro* data for the suppression of iNOS protein expression, iNOS mRNA expression, NF-κβ and Iκβα phosphorylation, NO release, LPS-stimulated phosphorylation of ERK-2 and PKCδ activation in N9 microglial cells. Figure 5 shows that tranilast does not interfere with LPS-induced activiation of NF-μB.

However, nitric oxide is not the only neurotoxic secretory product of microglia. See Rock et al. Table 2, page 119 for a list of the known secretory products of microglia, several of which in addition to nitric oxide, are neurotoxins. Also as discussed above, microglia play varying roles in the different conditions characterized by aberrant, unwanted or otherwise inappropriate microglial cell functional activity, such as NDDs, specifically those listed in claim 30. Nitric oxide production is not even

thought to be relevant to the onset of multiple sclerosis for example. Therefore, the inhibition of nitric oxide is by no means evidence that tranilast or compounds of formula (I) are enabled to prevent and treat NDDs since nitric oxide is just one of numerous neurotoxins produced by activated microglia.

Furthermore, Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of tranilast and certainly not compounds of formula (I) in general. Applicant's experimental data shows that in vitro, tranilast inhibits nitric oxide production. This is by no means indicative or predictive of *in vivo* activity. Pharmacological activity in general is a very unpredictable area, especially in dealing with the CNS. However, the specification is bereft of any data showing the functionality and/or biological activity of compounds of formula (I) other than tranilast. There are no working examples present for the treatment or prevention of any specific disease or disorder. Additionally, the disclosure is bereft of any information as to how the *in vitro* data with tranilast for one cell line correlates to the treatment or prevention of conditions characterized by aberrant, unwanted or otherwise inappropriate microglial cell functional activity.

The quantity of experimentation needed. Given the complexity of the invention, the large genus of compounds encompassed by the claims, the lack of specific guidance with regard to which compounds will retain functional activity, the lack of any *in vivo* data, and the lack of predictability in the pharmaceutical art, it will require undue and unpredictable experimentation in order to make an use the recited invention. First of all, one of skill in the art would need to determine individually whether or not tranilast

and compounds of formula (I) have any physiological effect *in vivo* on the CNS. One of skill in the art would also need to determine if tranilast and compounds of formula (I) are effective to treat each and every one of the myriad of the conditions recited in claim 30. It is exceedingly difficult to treat the disease without knowing its full scope of etiology and molecular mechanisms, which indicates that undue experiments are required. The specification fails to provide sufficient support of the broad use of tranilast and especially the use of compounds of formula (I) for the treatment and prevention of conditions characterized by aberrant, unwanted or otherwise inappropriate microglial cell functional activity, as a result necessitating one of skill to perform an exhaustive search for which diseases can be treated and/or prevented by administering tranilast or a compound of formula (I), in order to practice the claimed invention.

Genetech Inc. V. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated or prevented by the compound encompasses in the instant claims, with no assurance of success. Thus, rejection of claims 26-35 under 35 U.S.C. §112, first paragraph, is deemed proper.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Tamai et al. (American Heart Journal, 138(5), 1999, 965-975).

Applicant's claim a method of downregulating microglial cell functional activity (claims 1-5), in a mammal (claims 6-10) said method comprising contacting said cell or administering to a mammal, an effective amount of a compound of formula (I) or a pharmaceutically acceptable salt thereof. Dependent claims 11-15 further describe the compound of formula (I).

Tamai teaches the administration of tranilast to humans in a dosage of 600 or 300 mg/day (page 969, bottom of 1st column). Tamai does not recognize the downregulation of microglial cell functional activity, specifically nitric oxide synthesis, in a cell or mammal. However, it does recognize the association between the administration of tranilast and the down regulation of NOS activity. The sole active method step is the adminisration of the claimed compound. Applicant may have discovered the mode of action, however, the end result of downregulating microglial cell functional activity occurs as a consequence of administration of the drug even absent a understanding of the mode of action. Therefore the limitations of claims 1-15 are fully

met by the teachings of Tamai et al. As a result, rejection of claims 1-15 is deemed appropriate under 35 U.S.C 102(b).

Conclusion

Claims1-15 and 26-35 are rejected. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, Ph.D. whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached at (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615